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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,672	06/01/2001	Ryota Sugimoto	018961-054	8651

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EXAMINER

MATHEW, FENN C

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,672

Applicant(s)

SUGIMOTO, RYOTA

Examiner

Fenn Mathew

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has recited a method steps for forming the device, with the claims dependent on an apparatus claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Starck et al. (U.S. Patent No. 5,876,449). Starck et al. disclose an implantable tubular device formed substantially tubular (see abstract, line 3), and having a deformable portion formed on a peripheral surface thereof, with said deformable portion forming a predetermined angle with respect to an axial direction (see figs. 4a & 4b) of said device and being easy to deform in comparison with a remainder part of said device (column 5, lines 1-12).

5. Referring to claim 2, Starck et al. disclose an implantable device, wherein the device has a diameter so set that said device can be inserted into a lumen of a human body (column 1, lines 64-67), and capable of dilating radially (column 5, lines 13-24) upon application of a force acting radially outwardly from an interior of said tubular body (column 1, lines 22-31), the device comprising a plurality of wavy annular members (see fig. 1), each formed of a wavy element and arranged in an axial direction of the device, and connection portions (13) each connecting the wavy annular members to each other in the axial direction of the device wherein each of the wavy annular members has the deformable portion formed on a bent portion thereof not connected to the other wavy annular members in such a way that the deformable portion crosses the wavy annular members.
6. Referring to claim 3, Starck et al. disclose an implantable device wherein the deformable portions consists of a groove formed on an inner and outer surface of the device. (See figs. 4a, 4b).
7. Referring to claim 6, Starck et al. disclose a deformable portion formed in a plural number, and so formed that when the deformable portion is prolonged, the deformable portion continuously goes around a periphery of the device.
8. Referring to claim 8, Starck et al. disclose a device wherein the deformable portion is formed entirely on the device. (See figs. 4a, 4b).
9. Referring to claim 10, Starck et al. disclose a device wherein the device consists of a stent. (See abstract, line 1).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 4-5, 7, 9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449).

12. Referring to claim 4, the feature of the specific depth of the groove being set to 5-50% of the thickness of the device is a matter of obvious design choice.

13. Referring to claim 5, the feature of having the deformable portion form a 20-90 degree angle with the axial direction of the device is a matter of obvious design choice.

14. Referring to claim 7, Starck et al., disclose the claimed invention except for the angle at which the deformed portion with respect to the axial direction, which when stretched out creates a spiral on the periphery of the device. It would have been an obvious matter of design choice to have the deformed portion form an acute angle with respect to the axial direction in such a manner that when the device was stretched out, a spiral was formed around the periphery since applicant has not disclosed that having the deformable portion form a spiral periphery when the device is prolonged, solves any

stated problem or is for any particular purpose and it appears that the invention would perform equally well with modified embodiment described above in claim 6.

15. Referring to claim 9, the feature of having the interval between the deformable portions in the axial direction in the range of 0.01 – 1 mm, is a matter of obvious design choice.

16. Referring to claim 13, the feature of having groove depth set to 1-99% thickness of the device is a matter of obvious design choice.

17. Claims 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449) in view of Alt et al. (U.S. Patent No. 5,788,979). Starck et al., disclose the claimed invention except for having the device carrying a medicine, bioprosthetic material, or a biosynthesis material. Alt et al. teach a medicinal coating (column 8) that can be used for a stent (column 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Starck et al. with the medicinal coating taught by Alt et al. in order to deliver medicine to areas in the body once the device has been implanted within the body.

18. Referring to claim 19, Starck et al., as modified by Alt et al., discloses a medicine containing a pharmaceutical consisting of an antibiotic. (Alt et al. column 8, lines 25-27).

19. Claims 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449) in view of Alt et al. (U.S. Patent No. 5,788,979). Starck et al., disclose the claimed invention except for having at least one

part of the outer surface coated with a coating material made of a biocompatible material, a biodegradable material or a synthetic resin. Alt et al. disclose a coating comprising a biodegradable material (column 6, lines 59-64), which can be used for a stent (column 6, line 1).). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Starck et al. with the coating taught by Alt et al. in order to provide a more biocompatible implant that will not cause harm during degradation.

20. Referring to claim 17, Starck et al. as modified by Alt et al., discloses a coating that carries a medicine (column 8).

21. Referring to claim 18, Starck et al. as modified by Alt et al., discloses a coating material formed of a biodegradable material to which a medicine is added (column 8).

22. Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449) in view of Alt et al. (U.S. Patent No. 5,788,979).

Starck et al., disclose the claimed invention except for having at least one part of the outer surface of the deformable portion coated with a coating material made of a biocompatible material, a biodegradable material, or a synthetic resin. Alt et al. teach a biodegradable coating which can be used for a stent. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Starck et al. with the coating taught by Alt et al. on the outer surface of the deformable portion in order to provide a more biocompatible implant that will not cause harm during degradation.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Von Oepen U.S. Patent No. 6,068,656

Rolando et al. U.S. Patent No. 6,309,414

Wolinsky et al. U.S. Patent No. 6,331,189

Severini U.S. Patent No. 5,779,729

Bernacca et al. U.S. Patent No. 6,251,142


Banas et al. U.S. Patent No. 6,124,523

Jang U.S. Patent No. 6,241,760

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.


Denton D. DeMille
Primary Examiner

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July 1, 2002